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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,908	10/23/2000	Paul L. Hermonat	023533/0130	8355
22428	7590	04/21/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,908

Applicant(s)

HERMONAT, PAUL L.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4-20 and 46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2, 4-20 and 46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

This office action is in response to Applicant's paper filed 21 January 2004. Applicant's have been fully considered but they are persuasive in part and not persuasive in part. Claims 2, 4-20 and 46 are pending and under consideration.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, dated 21 October 2003, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 112

1. (Maintained) Claim 20 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro administration of the AAV Rep78 mutant for replication studies, does not reasonably provide enablement for in vivo therapeutic uses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The examiner acknowledges Applicant's arguments, however, they are not persuasive for the reasons stated in the previous office action. Again, there are no working examples or guidance that would lead one of ordinary skill to overcome the unpredictability taught in the art regarding therapeutic efficacy of viral vectors administered in vivo. The specification and arguments are all based on in vitro studies, and present no in vivo working example or guidance.

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Applicant poses several arguments that AAV is predictable, however, there is no disclosure as to the predictability of the AAV Rep78 mutant that is claimed. Thus, the rejection is maintained.

2. (Maintained) Claims 2, 4-20 and 46 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an AAV Rep78 mutant that demonstrates enhanced binding to HPV16 and decreasing binding to itself, does not reasonably provide enablement for increased or decreased binding to HIV and oncogenes as compared with wild type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The rejection is to the mutant and the lack of disclosure demonstrating that the mutant increases or decreases binding to HIV and oncogenes as compared with wild type. Applicant cites the disclosure at page 5, beginning at line 5, however, this merely states what known characteristics of the wild type. The examiner acknowledges that the disclosed references to the wild type cited on page 5 and its characteristics, however, this does not offer any guidance, predictability or working examples regarding the making or using of the mutant for the claimed increased or decreased binding to HIV and oncogenes as compared with the wild type. The mere ability to mutate the wild type does not convey mutant activity that increases or decreases binding to HIV and oncogenes as compared with the wild type. This line of claimed enablement imposes an undue experimental burden on one of ordinary skill to arbitrarily pick and choose mutations from the myriad of possibilities until the desired characteristics are acquired. Thus, the rejection is maintained.

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3. (Maintained) Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant's arguments are well taken, however, they have not obviated the rejection. It should be noted that the disclosure of the entire DNA sequence does not capitulate the virus mutants claimed. Thus, the requirement for disclosure is maintained as stated in the previous two office actions. Applicant must provide a statement regarding public knowledge and that the claimed virus mutants will be publicly available for the life of the patent (see MPEP§ 2402-2403 and 37 CFR 1.801-1.809 for all requirements for deposit).

It should be noted that due to examiner error in the previous office actions, claim 12 was excluded from the rejection as applied to claim 11, however, the essence of the rejection of claims 11 and 12 does not change and the rejection maintains the same claim language and does not constitute a new grounds for rejection.

4. (Withdrawn) Rejections of claims 7, 14-15 and 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn.

Conclusion

5. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
19 April 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER